K010471 p.1/2

JUN - 6 2001

Irvine Biomedical, Inc.

Special 510(k) Summary
Irvine Biomedical, Inc.
Afocus™ Steerable Electrophysiology Catheter System
Prepared February 19, 2001

Establishment Information

Submitter: Irvine Biomedicals, Inc.
2146A Michelson Drive
Irvine, CA 92612
Establishment Registration number: 2030404

Contact: James Farnworth
Director, RA/QA
Voice: 949-851-3053
Facsimile: 949-851-3062

Device Information

Trade Name: AFocus Steerable Electrophysiology Catheter System

Common Name: Deflectable Mapping Catheter

Classification Name: Catheter, Electrode Recording, or Probe, Electrode Recording
21 CFR 870.1220

Classification Panel: Cardiovascular

Predicate Device

IBI-1100 Steerable Electrophysiology Catheter System, K961924, April 11, 1997

2382 MORSE AVENUE • IRVINE, CALIFORNIA, USA • 92614
PHONE: 949-851-3053 • FAX: 949-851-3062

Device Description

The body of the AFocus Catheter System is constructed using radio-opaque braided Pebax™ thermoplastic elastomer. The electrodes are fabricated from a platinum-iridium alloy with the first electrode located at the distal tip and the other band electrodes following at predetermined distances. A connecting cable is used to connect the AFocus Catheter to electrogram devices.

The AFocus Catheter system is recognizable because of its specially designed distal end shape and shape orientation. The AFocus Catheter System includes a distal loop in a plane normal or perpendicular to the catheter body. The special circumferential shape or loop, featured on both the predicate device and the AFocus Catheter, allows the electrophysiologist to record the potentials of cardiac structures without changing the position of the catheter, thus possibly reducing the amount of time normally required to perform procedures.

The AFocus line of catheter products includes four different catheter models with shape or loop diameters of 15, 20, 25 and 30 mm. The 15 and 20 mm shape diameters are produced using a 4 french catheter body diameter. The 25 and 30 mm shape diameters are produced using a 5 french catheter body diameter. The 15 and 20 mm shape diameter catheters will include 10 electrodes. The 25 and 30 mm shape catheters will include 12 and 14 electrodes, respectively.

The AFocus line of catheters, like the predicate device, also features a steerable distal shape or loop diameter. The diameter of the shape or loop is adjustable or steerable by using the thumb to push or pull a piston located on the catheter handle.

Substantial Equivalence

The only difference between the predicate device and the AFocus Catheter is the orientation of the distal shape. While the special AFocus circumferential shape or loop is oriented perpendicular to the catheter body the distal shape of the predicate device is oriented in a plane parallel to the catheter body.

Indications for Use

IBI AFocus Steerable Electrophysiology Catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The AFocus Catheter System is designed to map the atrial regions of the heart.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 6 2001

Mr. James Farnworth
Director, RA/QA
Irvine Biomedical, Inc.
2146 A Michelson Drive
Irvine, CA 92612

Re: K010471
Trade Name: AFocus Electrophysiology Catheter System,
Models 81550, 81567
Regulation Number: 870.1220
Regulatory Class: II (two)
Product Code: DRF
Dated: May 4, 2001
Received: May 7, 2001

Dear Farnworth:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010471

Device Name: **AFocus Steerable Electrophysiology Catheter System**

Indications For Use:

IBI AFocus Steerable Electrophysiology Catheters are used for electrogram recording and cardiac stimulation during diagnostic electrophysiologic studies. The AFocus Catheter System is designed to map the atrial regions of the heart.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010471

Prescription Use _____ **OR** _____ **Over-The-Counter Use**
(Per 21 CFR 801.109)